REMARKS/ ARGUMENTS

Applicant has carefully studied the non-final Examiner's Action mailed December 21, 2010, having a shortened statutory period for response set to expire, with one-month extension, on April 21, 2011. These explanatory remarks are believed to be fully responsive to the Action. Accordingly, this important patent application is now believed to be in condition for allowance.

Applicant responds to the outstanding Action by centered headings that correspond to the centered headings employed by Office, to ensure full response on the merits to each finding of Office.

Claim Rejections - 35 U.S.C. § 112, first paragraph

Claims 1, 5-12, 14, and 16-18 stand rejected under 35 USC 112, first paragraph as failing to comply with the written description requirement. The Office found that the claims contain subject matter that was not described in the specification "as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention."[1] The Office found that the limitation that the human umbilical cord blood cells were administered without being cultured was not adequately supported in the original application.[2] The Office went on to find that the specification does not positively state that the mononuclear cells were not cultured in Example 1, and that the example merely shoes how to prepare mononuclear cells.[3] Likewise, the Office found that because paragraph [0055] provides for adding differentiating agents, that the disclosure of "'without treatment with a mobilization agent or differentiation agent' should be interpreted that without adding a mobilization agent or differentiation agent to the culture medium."[4]

Applicant notes that Example 1 provides methodology to isolate umbilical cord blood cells.[5] After disclosing the isolation of cells, Example 1 then states

> Group 1 consisted of 8 control rats with no interventions in order to determine whether any heart changes were due to increases in weight. Group 2 consisted of 15 rats with anterior wall ventricular infarctions from ligation of the left anterior descending coronary artery, and Group 3 consisted of 9 rats with anterior wall ventricular infarctions plus one million HUCBC that were circumferentially

[1] Page 2 of the non-final Office Action, dated December 21, 2010.
[2] Page 3 of the non-final Office Action, dated December 21, 2010.
[3] Page 4 of the non-final Office Action, dated December 21, 2010.
[4] Pages 5-6 of the non-final Office Action, dated December 21, 2010.
[5] See, pages 23-24, paragraphs [078]-[079] of the Application.

> injected directly in the periphery (i.e. border ischemic zones) of the ventricular infarction one hour after acute infarction.[6]

As can be seen from the quoted section, the HUCBC were injected into rats after isolation. Applicant notes that the specification provides for collection of cells and administration of the cells. There is no discussion of culturing of the cells. Moreover, Applicant submits that this, along with the remaining specification, indicate to one of skill in the art that the cells are administered without culturing or optionally with culturing, as provided in the attached declaration. For example, the Application states that some embodiments of the invention are compositions of hUCBC "in combination with plasma or fetal bovine serum, and DMSO."[7] In Example 2, the hUCBCs were plated and grown to 60% confluency.[8] However, in Example 1, the specification does not discuss any culturing conditions, which one of skill in the art would interpret as the cells were not cultured. Further,

> The compositions according to the present invention may be used without treatment with a mobilization agent or differentiation agent ("**untreated" *i.e.*, without further treatment** in order to promote differentiation of cells within the umbilical cord blood sample) or after treatment ("treated") with a differentiation agent or other agent[.][9]

Applicant submits that the disclosure in Example 1, which provides for isolation of HUCBC and administration of the cells into rats, indicates to one of skill in the art that the cells were not cultured in that example, as provided in the declaration.

Applicant therefore respectfully requests the Office withdrawn the 35 USC 112, first paragraph rejection of claims 1, 5-12, 14, and 16-18.

Conclusion

Applicant respectfully requests that a timely Notice of Allowance be issued in this case. If the Office is not fully persuaded as to the merits of Applicant's position, or if an Examiner's Amendment would place the pending claims in condition for allowance, a telephone call to the undersigned at (813) 925-8505 is requested.

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[6] Page 24, paragraph [081] of the Application.
[7] Page 13, paragraph [041] of the Application. See also, page 10, paragraph [031] of the Application ("In a further embodiment, the umbilical cord blood composition comprises a mononuclear cell fraction isolated form human umbilical cord blood; plasma or fetal bovine serum, and DMSO.").
[8] Page 25, paragraphs [086] of the Application.
[9] Page 16, paragraph [050] of the Application (emphasis added).

Very respectfully,

SMITH & HOPEN

/robert varkonyi/

By:_____

Dated: April 20, 2011
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CERTIFICATE OF ELECTRONIC TRANSMISSION

(37 C.F.R. 2.190 (b))

I HEREBY CERTIFY that this correspondence is being electronically transmitted to the Patent and Trademark Office through EFS Web on April 20, 2011.

/lauren reeves/

Date: April 20, 2011

Lauren Reeves